AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, or claims in the application.

In the Claims

1. (Currently amended) A method for treating hyperplasia of non-cancerous cells in a blood vessel of a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein ~~a protein~~, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

2. (Cancelled)

3. (Original) A method according to claim 1 wherein said hyperplasia occurs in blood vessel neointima.

4. (Original) A method according to claim 1 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

5. (Original) A method according to claim 4 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

6. (Original) A method according to claim 1 wherein said composition is administered systemically.

7. (Original) A method according to claim 6 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

8. (Original) A method according to claim 1 wherein said composition is administered before, during or after the occurrence of said hyperplasia.

9. (Currently amended) A method for reducing neointimal hyperplasia of non-cancerous cells associated with vascular interventional procedure(s) in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising at least one amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein ~~a protein~~, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

10. (Original) A method according to claim 9 wherein said procedure comprises angioplasty, stenting or atherectomy.

11. (Original) A method according to claim 9 wherein said composition is administered before, during or after the vascular interventional procedure.

12. (Original) A method according to claim 9 wherein said composition is administered at the time of the vascular interventional procedure.

13. (Original) A method according to claim 9 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

14. (Original) A method according to claim 13 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

15. (Original) A method according to claim 9 wherein said composition is administered systemically.

16. (Original) A method according to claim 9 wherein said composition is administered by deployment of a stent containing said at least one drug coated thereon.

17. (Currently amended) A method to reduce proliferation and cell migration in a subject undergoing a vascular interventional procedure, said method comprising systemically administering to said subject before, during or after said procedure, a formulation comprising (i) an amorphous drug in nanoparticle form, wherein said drug inhibits proliferation and cell migration, and (ii) a

biocompatible protein, wherein said drug is coated with a coating consisting essentially of said protein ~~a protein~~, and wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

18-28. (Cancelled).

29. (Currently amended) A method to reduce the toxicity of a drug that inhibits proliferation and migration of non-cancerous cells in a blood vessel, said method comprising combining said drug, in amorphous form and in the form of nanoparticles, with a biocompatible protein, wherein said drug is coated with a coating consisting essentially of said protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

30. (Cancelled).

31. (Previously presented) The method according to claim 1, wherein said drug is a taxane or analog or homolog thereof.

32. (Previously presented) The method according to claim 31, wherein said drug is a taxane.

33. (Previously presented) The method according to claim 32, wherein said taxane is paclitaxel.

34. (Previously presented) The method according to claim 1, wherein said drug is an epothilone or an analog or homolog thereof.

35. (Previously presented) The method according to claim 34, wherein said drug is an epothilone.

36. (Previously presented) The method according to claim 1, wherein said drug is a rapamycin or analog or homolog thereof.

37. (Previously presented) The method according to claim 36, wherein said drug is a rapamycin.

38. (Previously presented) The method according to claim 1, wherein said protein is albumin.

39. (Previously presented) The method according to claim 9, wherein said drug is a taxane or analog or homolog thereof.

40. (Previously presented) The method according to claim 39, wherein said drug is a taxane.

41. (Previously presented) The method according to claim 40, wherein said taxane is paclitaxel.

42. (Previously presented) The method according to claim 9, wherein said drug is an epothilone or an analog or homolog thereof.

43. (Previously presented) The method according to claim 42, wherein said drug is an epothilone.

44. (Previously presented) The method according to claim 9, wherein said drug is a rapamycin or analog or homolog thereof.

45. (Previously presented) The method according to claim 44, wherein said drug is a rapamycin.

46. (Previously presented) The method according to claim 9, wherein said protein is albumin.

47. (Previously presented) The method according to claim 17, wherein said drug is a taxane or analog or homolog thereof.

48. (Previously presented) The method according to claim 47, wherein said drug is a taxane.

49. (Previously presented) The method according to claim 48, wherein said taxane is paclitaxel.

50. (Previously presented) The method according to claim 17, wherein said drug is an epothilone or an analog or homolog thereof.

51. (Previously presented) The method according to claim 50, wherein said drug is an epothilone.

52. (Previously presented) The method according to claim 17, wherein said drug is a rapamycin or analog or homolog thereof.

53. (Previously presented) The method according to claim 52, wherein said drug is a rapamycin.

54. (Previously presented) The method according to claim 17, wherein said protein is albumin.

55. (Previously presented) The method according to claim 17, wherein said procedure comprises angioplasty, stenting or atherectomy.

56. (New) The method according to claim 1 wherein said composition is administered by deployment of a stent containing at least one drug coated thereon.

57. (New) The method according to claim 1 wherein said nanoparticles do not have a polymeric core matrix.

58. (New) The method according to claim 1 or 57 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

59. (New) The method according to claim 38 wherein said albumin is human serum albumin.

60. (New) The method according to claim 9 wherein said nanoparticles do not have a polymeric core matrix.

61. (New) The method according to claim 9 or 60 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

62. (New) The method according to claim 15 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

63. (New) The method according to claim 46 wherein said albumin is human serum albumin.

64. (New) The method according to claim 17 wherein said procedure comprises angioplasty, stenting or atherectomy.

65. (New) The method according to claim 17 wherein said composition is administered before, during or after the vascular interventional procedure.

66. (New) The method according to claim 17 wherein said composition is administered at the time of the vascular interventional procedure.

67. (New) The method according to claim 17 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

68. (New) The method according to claim 67 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

69. (New) The method according to claim 17 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

70. The method according to claim 17 wherein said nanoparticles do not have a polymeric core matrix.

71. (New) The method according to claim 17 or 70 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

72. (New) The method according to claim 54 wherein said albumin is human serum albumin.

73. (New) The method according to any one of claims 7, 62, and 69, wherein said composition is administered intra-arterially.

74. (New) The method according to claim 73 wherein said composition is administered to a coronary artery.

75. (New) The method according to claim 73 wherein said composition is administered to a femoral artery.

76. (New) The method according to claim 73 wherein said composition is administered to a carotid artery.

77. (New) The method according to any one of claims 1, 9, and 17, wherein said composition is administered in conjunction with a device for delivery of a pharmacological agent.

78. (New) The method according to claim 77 wherein said device is a balloon catheter.